CLAIMS

We claim:

1. A polymeric composition having improved capability to solubilize a drug in a hydrophilic environment, comprising: a biodegradable ABA-type, or BAB-type block copolymer, comprising:

i) 50.1 to 65 % by weight of a biodegradable, hydrophobic A polymer block comprising a biodegradable polyester, and

ii) 35 to 49.9 % by weight of a hydrophilic B polymer block comprising a polyethylene glycol (PEG), and wherein the block copolymer has a weight averaged molecular weight of between 1500 to 3099 Daltons,

with the proviso that said polymeric composition when formed as an aqueous polymer solution, is a free flowing liquid at body temperatures.

2. The polymeric composition according to Claim 1 wherein the biodegradable polyester of the hydrophobic A polymer block is synthesized from monomers selected from the group consisting of D, L-lactide, D-lactide, L-lactide, D, L-lactic acid, D-lactic acid, L-lactic acid, glycolide, glycolic acid, ε-caprolactone, ε-hydroxy hexanoic acid, and copolymers thereof.

3. The polymeric composition according to Claim 1 wherein the A polymer block comprises between about 20 to 100 mole percent lactide or lactic acid, and between about 0 to 80 mole percent glycolide or glycolic acid.

4. A biodegradable polymeric drug delivery composition capable of solubilizing a drug in a hydrophilic environment to form a solution, comprising:

(a) an effective amount of a drug; and

(b) a biodegradable ABA-type, or BAB-type block copolymer comprising:

i) 50.1 to 65 % by weight of a biodegradable, hydrophobic A polymer block comprising a biodegradable polyester, and

ii) 35 to 49.9 % by weight of a hydrophilic B polymer block comprising a polyethylene glycol (PEG), and wherein the block copolymer has a weight-averaged molecular weight of between 1500 to 3099 Daltons,

wherein said composition forms a free flowing liquid at body temperatures in an aqueous environment.

5. The polymeric drug delivery composition according to Claim 4 wherein the biodegradable polyester of the hydrophobic A polymer block is synthesized from monomers selected from the group consisting of D, L-lactide, D-lactide, L-lactide, D, L-lactic acid, D-lactic acid, L-lactic acid, glycolide, glycolic acid, ε-caprolactone, ε-hydroxy hexanoic acid, and copolymers thereof.

6. The polymeric drug delivery composition according to Claim 4 wherein the A polymer block comprises between about 20 to 100 mole percent lactide or lactic acid, and between about 0 to 80 mole percent glycolide or glycolic acid.

7. The polymeric drug delivery composition according to Claim 4 wherein the drug content is 10^{-6} to 100% of the total triblock copolymer weight.

8. A biodegradable polymer solution as a drug delivery vehicle capable of solubilizing a drug in a hydrophilic environment, comprising: a functional concentration of a biodegradable ABA-type, or BAB-type block copolymer and an aqueous solution, said block copolymer comprising:

i) 50.1 to 65 % by weight of a biodegradable, hydrophobic A polymer block comprising a biodegradable polyester, and

ii) 35 to 49.9 % by weight of a hydrophilic B polymer block comprising a polyethylene glycol (PEG), and wherein the block copolymer has a weight-averaged molecular weight of between 1500 to 3099 Daltons;

and wherein said polymer solution is a free flowing liquid at body temperatures.

9. The polymeric solution according to Claim 8 wherein said functional concentration of said copolymer is between about 1 to 50% by weight of said polymer solution.

10. The polymeric composition according to Claim 8 wherein the biodegradable polyester of the hydrophobic A polymer block is synthesized from monomers selected from the group consisting of D, L-lactide, D-lactide, L-lactide, D, L-lactic acid, D-lactic acid, L-lactic acid, glycolide, glycolic acid, ε-caprolactone, ε-hydroxy hexanoic acid, and copolymers thereof.

11. The polymeric composition according to Claim 8 wherein the A polymer block comprises between about 20 to 100 mole percent lactide or lactic acid, and between about 0 to 80 mole percent glycolide or glycolic acid.

12. A biodegradable drug solution comprising:

(a) an effective amount of a drug solubilized in a polymer solution comprising;

(1) a functional concentration of a biodegradableABA-type, or BAB-type block copolymer capable of solubilizing said drug in a hydrophilic environment, comprising:

i) 50.1 to 65 % by weight of a biodegradable, hydrophobic A polymer block comprising a biodegradable polyester, and

ii) 35 to 49.9 % by weight of a hydrophilic B polymer block comprising a polyethylene glycol (PEG), and wherein the tri-block copolymer has a weight-averaged molecular weight of between 1500 to 3099 Daltons; and

(2) an aqueous solution,

with the proviso that said polymer solution is a free flowing liquid at a body temperature.

13. The biodegradable aqueous polymeric drug solution according to Claim 12 further comprising excipients, additives, buffers, osmotic pressure adjusting agents, antioxidants, preservatives, drug stabilizing agents or equivalents thereof.

14. The biodegradable aqueous polymeric drug solution according to Claim 12 wherein the functional concentration of said copolymer is between about 1 to 50% by weight of said polymer solution.

15. The biodegradable aqueous polymeric drug solution according to Claim 12 wherein the drug content is 10^{-6} to 100% of the total triblock copolymer weight.

16. The biodegradable aqueous polymeric drug solution according to Claim 12 wherein the biodegradable polyester of the hydrophobic A polymer block is synthesized from monomers selected from the group consisting of D, L-lactide, D-lactide, L-lactide, D, L-lactic acid, D-lactic acid, L-lactic acid, glycolide, glycolic acid, ε-caprolactone, ε-hydroxy hexanoic acid, and copolymers thereof.

17. The biodegradable aqueous polymeric drug solution according to Claim 12 wherein the A-block comprises between about 20 to 100 mole percent lactide or lactic acid and between about 0 to 80 mole percent glycolide or glycolic acid.

18. A method for administering a drug to a warm blooded animal, comprising

(1) providing a biodegradable polymeric drug delivery composition comprising:

(a) an effective amount of a drug; and

(b) a biodegradable ABA-type, or BAB-type block copolymer comprising:

i) 50.1 to 65 % by weight of a biodegradable, hydrophobic A polymer block comprising a biodegradable polyester, and

ii) 35 to 49.9 % by weight of a hydrophilic B polymer block comprising a polyethylene glycol (PEG), and wherein the block copolymer has a weight-averaged molecular weight of between 1500 to 3099 Daltons,

with the proviso that said polymeric composition forms a free flowing liquid at body temperature in an aqueous environment, and

(2) administering said composition to said warm blooded animal.

19. The method according to Claim 18 wherein the biodegradable polyester of the hydrophobic A polymer block is synthesized from monomers selected from the group consisting of D, L-lactide, D-lactide, L-lactide, D, L-lactic acid, D-lactic acid, L-lactic acid, glycolide, glycolic acid, ε-caprolactone, ε-hydroxy hexanoic acid, and copolymers thereof.

20. The method according to Claim 18 wherein the A polymer block comprises between about 20 to 100 mole percent lactide or lactic acid, and between about 0 to 80 mole percent glycolide or glycolic acid.

21. The method according to Claim 18 wherein the drug content is 10^{-6} to 100% of the total triblock copolymer weight.

22. The method according to Claim 18 wherein said administration is by parenteral, ocular, topical, inhalation, transdermal, vaginal, buccal, transmucosal, transurethral, rectal, nasal, oral, peroral, pulmonary or aural means.

23. A method for administering a drug to a warm blooded animal, comprising

(1) providing a biodegradable polymeric drug solution comprising an effective amount of a drug solubilized in a polymer solution comprising;

(a) a functional concentration of a biodegradable ABA-type, or BAB-type block copolymer capable of solubilizing said drug in a hydrophilic environment, comprising:

i) 50.1 to 65 % by weight of a biodegradable, hydrophobic A polymer block comprising a biodegradable polyester, and

ii) 35 to 49.9 % by weight of a hydrophilic B polymer block comprising a polyethylene glycol(PEG), and wherein the tri-block copolymer has a weight-averaged molecular weight of between 1500 to 3099 Daltons; and

(b) an aqueous solution; with the proviso that said polymer solution is a free flowing liquid at body temperatures, and;

(2) administering said drug solution to said warm blooded animal.

24. The method according to Claim 23 wherein the functional concentration of said copolymer is between about 1 to 50% by weight of said polymer solution.

25. The method according to Claim 23 wherein the biodegradable polyester of the hydrophobic A polymer block is synthesized from monomers selected from the group consisting of D, L-lactide, D-lactide, L-lactide, D, L-lactic acid, D-lactic acid, L-lactic acid, glycolide, glycolic acid, ε-caprolactone, ε-hydroxy hexanoic acid, and copolymers thereof.

26. The method according to Claim 23 wherein the A-block comprises between about 20 to 100 mole percent lactide or lactic acid and between about 0 to 80 mole percent glycolide or glycolic acid.

27. The method according to Claim 23 wherein the drug content is 10^{-6} to 100% of the total triblock copolymer weight.

28. The method according to Claim 23 wherein said administration is by intramuscular, intraperitoneal, intra-abdominal, subcutaneous, intrathecal, intrapleural, intravenous or intraarterial means.

29. A method for enhancing the solubility of a drug, comprising

1) preparing a polymeric composition comprising a functional concentration of a biodegradable ABA-type, or BAB-type block copolymer, comprising:

i) 50.1 to 65 % by weight of a biodegradable, hydrophobic A polymer block comprising a biodegradable polyester, and

ii) 35 to 49.9 % by weight of a hydrophilic B polymer block comprising a polyethylene glycol (PEG), and wherein the block copolymer has a weight averaged molecular weight of between 1500 to 3099 Daltons,

2) admixing the polymeric composition with a drug; and

3) admixing the drug containing polymeric composition with an aqueous solution to obtain a drug solution that remains a free flowing liquid at body temperatures.

30. The method according to Claim 29 wherein the functional concentration of said copolymer is between about 1 to 50% by weight of said polymer solution.

31. The method according to Claim 29 wherein the biodegradable polyester of the hydrophobic A polymer block is synthesized from monomers selected from the group consisting of D, L-lactide, D-lactide, L-lactide, D, L-lactic acid, D-lactic acid, L-lactic acid, glycolide, glycolic acid, ε-caprolactone, ε-hydroxy hexanoic acid, and copolymers thereof.

32. The method according to Claim 31 wherein the A-block comprises between about 20 to 100 mole percent lactide or lactic acid and between about 0 to 80 mole percent glycolide or glycolic acid.

33. The method according to Claim 29 wherein the drug content is 10^{-6} to 100% of the total triblock copolymer weight.

34. A method for enhancing the solubility of a drug, comprising

1) preparing a polymeric composition comprising a functional concentration of a biodegradable ABA-type, or BAB-type block copolymer, comprising:

i) 50.1 to 65 % by weight of a biodegradable, hydrophobic A polymer block comprising a biodegradable polyester, and

ii) 35 to 49.9 % by weight of a hydrophilic B polymer block comprising a polyethylene glycol (PEG), and wherein the block copolymer has a weight averaged

molecular weight of between 1500 to 3099 Daltons,

2) admixing said composition with an aqueous solution to form a polymeric solution that remains a free flowing liquid at body temperatures, and

3) admixing said polymer solution with a drug to form a drug solution.

35. The method according to Claim 34 wherein the functional concentration of said copolymer is between about 1 to 50% by weight of said polymer solution.

36. The method according to Claim 34 wherein the biodegradable polyester of the hydrophobic A polymer block is synthesized from monomers selected from the group consisting of D, L-lactide, D-lactide, L-lactide, D, L-lactic acid, D-lactic acid, L-lactic acid, glycolide, glycolic acid, ε-caprolactone, ε-hydroxy hexanoic acid, and copolymers thereof.

37. The method according to Claim 34 wherein the A-block comprises between about 20 to 100 mole percent lactide or lactic acid and between about 0 to 80 mole percent glycolide or glycolic acid.

38. The method according to Claim 34 wherein the drug content is 10^{-6} to 100% of the total triblock copolymer weight.

39. A method for enhancing the solubility of a drug, comprising

1) preparing a polymeric composition comprising a functional concentration of a biodegradable ABA-type, or BAB-type block copolymer, comprising:

i) 50.1 to 65 % by weight of a biodegradable, hydrophobic A polymer block

comprising a biodegradable polyester, and

ii) 35 to 49.9 % by weight of a hydrophilic B polymer block comprising a polyethylene glycol (PEG), and wherein the block copolymer has a weight averaged molecular weight of between 1500 to 3099 Daltons,

2) admixing a drug with an aqueous solution to form a drug-aqueous solution mixture, and

3) admixing said polymer composition with said drug-aqueous solution mixture to form a drug polymeric solution that remains as a free flowing liquid at a body temperature.

40. The method according to Claim 39 wherein the functional concentration of said copolymer is between about 1 to 50% by weight of said polymer solution.

41. The method according to Claim 39 wherein the biodegradable polyester of the hydrophobic A polymer block is synthesized from monomers selected from the group consisting of D, L-lactide, D-lactide, L-lactide, D, L-lactic acid, D-lactic acid, L-lactic acid, glycolide, glycolic acid, ε-caprolactone, ε-hydroxy hexanoic acid, and copolymers thereof.

42. The method according to Claim 39 wherein the A-block comprises of between about 20 to 100 mole percent lactide or lactic acid and between about 0 to 80 mole percent glycolide or glycolic acid.

43. The method according to Claim 39 wherein the drug content is 10^{-6} to 100% of the total tri block copolymer weight.